REMARKS

Entry of the foregoing and favorable reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. Section § 1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, Table 1 in the specification has been amended to correct the inadvertent omission of sequence No. 7. Claims 1-6, 12-19, 21, 24 and 62 have been amended. The phrase "inserted therein" in each of claims 12-16 has been deleted. In claim 62, the recitation "pharmaceutical" has been deleted, and the recitation of a "carrier or excipient" has been added, support for which is set forth on page 63, line 32 of the specification. No new matter has been added. Claims 7 to 11, 22, 23, 25, 27 to 61 and 63 to 73 have been withdrawn as being directed to a non-elected invention. Claims 31 and 54 have been amended solely to eliminate the multiple dependencies, and thus greatly reduce the total claim count. Entry of these two amendments strictly for this purpose is respectfully requested. Applicants reserve their right to file a divisional application directed to the non-elected inventions. Applicants submit that no new matter has been added via this amendment.

Claims 1 to 6, 12 to 21, 24, 26 and 62 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection has been rendered moot-in-part by amendment and is being traversed-in-part.

Claims 2, 4 and 5 have been amended to become independent claims, solely to expedite the prosecution of the present application. Applicants submit that the term "consisting essentially of" is a legal term with an established meaning, in that it serves to exclude ingredients that materially affect the basic and novel characteristics of the claimed invention. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Applicants are aware of no authority that

requires an explicit definition of the term to be provided in the specification. See, *PPG Industries v. Guardian Industries Corp.*, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) (holding that the patentee was entitled to produce extrinsic evidence to show how one of skill in the art would interpret the term). Applicants submit that persons skilled in the art would be able to determine the metes and bounds of the claims, when read in light of the specification and the prior art.

The term "complementary" when referring to an amino acid has been deleted from the claims.

Table 1 has been amended to include SEQ ID No. 7, and is now consistent with the description of the specification e.g., page 12. Applicants submit that the error was obvious, especially in view of the missing SEQ ID No. 7 and that SEQ ID No. 39 had two different inconsistent entries in the Table.

Applicants respectfully disagree with the Examiner's contention that the translation product of SEQ. ID NO:58 does not match either polypeptide designated as SEQ ID NO:20 or 21. In SEQ ID NO. 58, there are 137 nucleotides that are shown. Therefore 45 amino acids are translated. The first and the last nucleotides in this sequence are not translated. Therefore, SEQ ID NO. 58 in fact encodes the protein sequence of SEQ ID No. 20, which starts with Pro(ccg) Pro (ccc) Leu (ttg) Arg (cga) etc.

Claims 18 and 19 have been amended by replacing the term "and" with "or." Also, claims 18 and 19 are each multiply dependent on claims 12 to 16. Therefore, Applicants submit that these claims are not indefinite.

Claim 24 has been amended to recite a composition comprising a set of nucleic acids encoding polypeptides, which should render this particular rejection moot. Claim 26 is directed to complexes between the polypeptides, and not the two nucleic acids. The complexes are described e.g., on page 33 of the present specification, as being a SID polypeptide and a

second polypeptide that binds specifically with the SID polypeptide. Thus, when read in light of the specification the term "complex" is believed to have a clear and definite meaning.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

Claims 17 and 19 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. For the following reasons, this rejection is respectfully traversed.

In rendering this rejection the Examiner deems that the plasmids recited in claims 17 to 19, i.e., plasmids pACTllst, pAS2ΔΔ, pT25, pKT25, pUT18, pUT18C, pP6 and pB5, were not known and not available to the public, or obtainable by a repeatable method set forth in the specification. Applicants disagree with the Examiner for the following reasons.

A person skilled in the art could easily reproduce the plasmids without undue experimentation. All of these plasmids or the plasmids from which they were derived were known prior to the priority date of the present invention, as evidenced by the enclosed publications.

More specifically, pAS2ΔΔ is described in WO 99/42612 published August 26, 1999. On page 7 of this reference, it is stated that the pAS2ΔΔ vector was derived from pAS2 plasmid as follows: the *CHY2* gene was deleted by partial *Eco*RV digestion followed by a self-ligation. The HA epitope was then deleted by removing the *Eco*Rl-*Nde*l fragment.

pAS2 was publicly available and sold by Clontech. The sequence was also known as evidenced by the enclosures.

pACTllst is derived from pACTll, which sequence was known in 1995 and described in Durfee et al, Genes Dev. 7:555-569 (1993). pACTllst was prepared by adding three stop codons before the *XHo*l site. See page 7 of W099/42612.

The pT25 plasmid is derived from pACYC184 plasmid as

described e.g., in Figure 6 of the present application. The pACYC184 plasmid is described in *J. Bacteriol.* (1978) 134, 1141-1156) and *Nucleic Acids Res.* (1988) 16, 355. Furthermore, pACYC184 plasmid is commercialized by Fermentas or DSMZ.

The pKT25 plasmid is derived from pSU40 plasmid as described e.g., in Figure 7 of the present application. Furthermore, the pSU40 plasmid is described in the publication *Gene* 102:75-78 (1991).

The pUT18 plasmid is described in the publication Plasmid (1994) 31(3), 297-299 and its sequence is also known.

The pUT18C plasmid is identical to pUT18 plasmid above, except with respect to the position and sequence of MSC which are exemplified e.g., in Figure 5 of the present application.

The pP6 plasmid is derived from plasmid pGAD3S2X and is altered according to the description in the specification e.g., on page 66. pGAD3S2X was available to the public prior to the filing date of the present invention as indicated in J. Biol. Chem Vol. 272, Issue 40, 26026-26035 (1998).

The pB5 plasmid is described at least in Figure 12 of the present application is derived from pAS2ΔΔ plasmid described in Figure 2, but the *Nco*l/*Sal*l polylinker fragment is replaced with SEQ ID No. 154. This construct is described at least on page 68 of the specification.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

Claims 1-6, 12-21, 24, 26 and 62 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. For the following reasons, this rejection is respectfully traversed.

First of it should be pointed out that the specification clearly enables several uses for the nucleic acid sequences and compositions containing them e.g., to create bait/prey libraries (page 8), to obtain the particular Selected Interacting Domain

SID® (page 10) and to produce recombinant vectors (Page 21) to be used to select modulating compounds (Page 37). Various cellular detection assays are described at least on page 52 of the specification, as well as other detection methods, which are described at least on pages 52 to 61 of the specification.

Second, it appears that the Examiner is of the opinion that the specification is non-enabling because explicit detail is not given as to why the detection of NS4B / NS5A would be of interest; that the specification does not disclose that an interaction actual occurs between the natural proteins; and that the gene therapy treatments for virus infection were not recognized as successful in the art at the time the invention was made. Applicants disagree with the Examiner's opinion for the following reasons.

It should be noted that Claim 62 has been amended to recite a composition, as opposed to a "pharmaceutical" composition. Thus, the Examiner's comments with respect to gene therapy should be rendered moot with respect to claim 62.

Concerning the other enablement rejections, it should be pointed out that enablement is not measured in a vacuum but should be viewed with respect to the skilled artisan at the time of the filing of the application. See, S3 *Inc. v. nVIDIA Corp.*, 59 USPQ2d 1745, 1749 (Fed.Cir. 2001) ("The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention.").

Therefore, Applicants submit that the structural proteins of hepatitis C virus were well known in the art at the time of present invention was made, as evidenced by the description of the state of the art set forth in the present specification.

Thus, it was known in the art prior to the at the time of present invention was made that the hepatitis C virus encodes a

large polyprotein that is proteolytically cleaved into at least ten distinct products in the order of:

NH_2-C-E1I-E2-p7-N52-N53-NS4A-NS4B-NS5A-NS5B-COOH

It was also known that the structural proteins of hepatitis C virus code for the core (C) and envelope (E1-E2) regions while the non-structural regions (NS) code for N52-N53-NS4A, NS4B, NS5A-NS5B.

It was also known prior to time of present invention was made that NS5B protein of the hepatitis C virus (HCV) was an RNA-dependent RNA polymerase that is required for replication of the viral genome. It was also known that the non structural proteins of HCV form a large replicase complex to direct viral RNA replication.

Thus, the demonstration of the protein protein interaction between NS4B/NS5A and NS5B indicates that this complex is involved in the replication of the viral genome and the assembly of the virion particles. This virus specific function is essential for HCV replication and therefore the skilled artisan would appreciate that this interaction could be used to detect HCV replication.

Moreover, it is set forth e.g., in the examples of the specification, that the prey/bait nucleic acid libraries are prepared from a genomic DNA library from the pathogenic strain H77 of HCV (see, page 8). Thus, the Examiner's contention that the interaction does not occur between natural proteins is incorrect.

In conclusion, Applicants submit that the presently claimed invention is enabling when viewed in light of the specification and what was known in the art at the time the present invention was made.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

Claims 1-6, 12-16, 20, 21, 24 and 26 have been rejected

under 35 U.S.C. § 102(b) as being anticipated by Yanagi, *et al.* ("*Yanagi*"). Applicants respectfully submit that *Yanagi* does not anticipate the claimed invention. The teachings of Yanagi are mentioned on page 8 of the specification, specifically in the context of using the genome of the H77 strain of HCV (i.e., the full-length cDNA clone) disclosed in Yanagi, as a starting material in the preparation of a DNA library, the products of which are used to produce the so-called "prey" nucleic acids of the present invention. Clearly, in view of these teachings, persons skilled in the art would understand that the claim term "consisting essentially of" would be interpreted to exclude the full-length cDNA clone of H77 strain of HCV. That is, this transitional term is used in the claims e.g., to further define SEQ ID NOS:58 and 132, as not including the entire naturally occurring sequence in which they are contained. In view of the foregoing, reconsideration and withdrawal of the rejection are respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

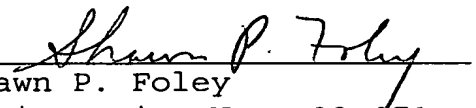
If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge

Deposit Account No. 12-1095 therefor.

Dated: March 4, 2004

Respectfully submitted,

By 

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